



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,334	02/08/2001	Carsten Sjoeholm	6092.200-US	9041
25908	7590	06/15/2004	EXAMINER	
NOVOZYMES NORTH AMERICA, INC.			WEBER, JON P	
500 FIFTH AVENUE			ART UNIT	
SUITE 1600			PAPER NUMBER	
NEW YORK, NY 10110			1651	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/779,334	Applicant(s) SJOEHOLM ET AL.	
	Examiner Jon P Weber, Ph.D.	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-49 is/are pending in the application.
4a) Of the above claim(s) 42-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-35,37 and 39-41 is/are rejected.
- 7) ☒ Claim(s) 36 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

The response with amendments filed 25 May 2004 has been received and entered. Claims 28-49 have now been presented for examination.

Election/Restrictions

Newly submitted claims 42-49 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 42-49 are directed to a method of use, which has not previously been examined or considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 28-41 remain to be considered on the merits.

In view of *In re Ochiai*, should an allowable product be determined, applicants are entitled to rejoinder of methods claims of the same scope and otherwise allowable.

Claim Rejections - 35 USC § 102

Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiller (US 4,239,750), Hiller (US 4,225,584) or Hiller (US 4,218,437).

Claims 28-32 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehmann et al. (US 4,062,732).

It is argued that the claims require that the protease in the feed additive is both a subtilisin and acid stable. It is urged that the organisms in the references produce many acid-stable proteases, not just subtilisins. It is argued that none of the specific proteases mentioned in these references is a subtilisin.

The claims do not require that the acid-stable protease is a subtilisin. The language of the claim is specifically recited in the alternative “and/or”, that is, the acid-stable protease just has to be inhibited by the *Streptomyces* subtilisin inhibitor. Further, it has not been established by facts or other evidence that the proteases of the prior art references are **not** subtilisins. This is argument by counsel only. The instant disclosure does not define what is meant by a subtilisin; hence, it is assumed that a subtilisin is a protease that has properties of a subtilisin, a low molecular weight serine protease of microbial origin. From the disclosure of the references, these proteases seem to meet this limitation. The references are silent with respect to the sensitivity to the *Streptomyces* subtilisin inhibitor; however, this is considered an inherent property of subtilisins. Absent concrete evidence that the prior art acid-stable proteases are not subtilisins, these proteases are considered to be within the scope of the instant claims.

Applicant's arguments filed 25 May 2004 have been fully considered but they are not persuasive. The rejections under 35 U.S.C. 102 are adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 103

Claims 28-35, 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller (US 4,239,750), Hiller (US 4,225,584), Hiller (US 4,218,437) or Lehmann et al. (US

Art Unit: 1651

4,062,732) in view of Outtrup et al. (US 5,597,720), Knap et al. (US 6,558,693), Grinberg et al. (SU 779,383) and Isono et al. (US 3,652,399).

Knap et al. (US 6,558,693) establish that feed enhancing enzymes include phytases, proteases, α -galactosidases, β -glucanases, β -galactosidases, cellulases, xylanases, β -galactanases and β -galactosidases (column 1, lines 43-47).

Kuznetsova et al. (SU 779,383) disclose acid-protease from *Acremonium chrysogenum*.

Isono et al. (US 3,652,399) disclose acid stable proteinase (to pH 5.0; see Fig. 5) from *Fusarium oxysporum* IFO 4471.

The response argues again that the proteases of the primary references are not subtilisins. It is urged that Hiller (US 4,218,437) state that the acid protease did not make much difference to feed utilization or end weight.

The quote from Hiller (US 4,218,437), example 2, is taken out of context. Hiller (US 4,218,437) states that the combination of the antibiotic and acid-stable protease provides an unexpected and synergistic result. This synergism is reiterated in each of examples 3, 4, 5, 6 and 7. Hence, the advantage of the acid-stable protease is to enhance the effect of the antibiotic in a synergistic manner.

The results in Hiller (US 4,218,437) do not show any particular advantage of one acid-stable protease over another. Hence, it is still considered obvious to substitute one acid-stable protease for another.

Knap et al. (US 6,558,693), Kuznetsova et al. (SU 779,383) and Isono et al. (US 3,652,399) disclose additional embodiments in new claims 35, 37 and 41.

Art Unit: 1651

Applicant's arguments filed 25 May 2004 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

Allowable Subject Matter

Claims 36 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Acid-stable proteases from either of *Paecilomyces lilacinus* or *Acremonium kiliense* are not known.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

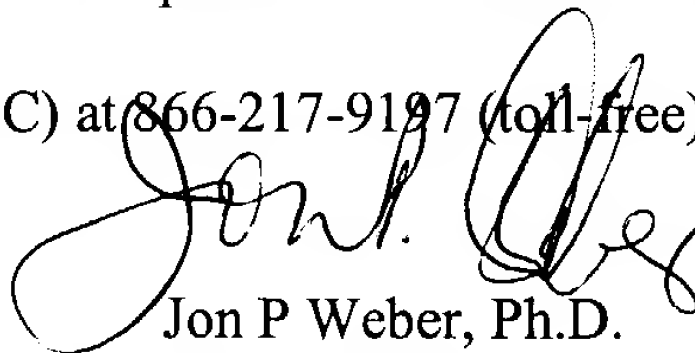
Art Unit: 1651

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
9 June 2004